UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' JOINT MOTION TO EXCLUDE OPINIONS OF PHILIP RUSS

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Pursuant to Federal Rules of Evidence 702 and 703, Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis Pharma, Inc., Actavis LLC, Torrent Pharmaceuticals Ltd., Torrent Pharma Inc., Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare US, LLC (collectively, "Defendants") submit this Memorandum of Law in Support of Defendants' Joint Motion to Exclude Opinions of Philip Russ ("Motion").

INTRODUCTION

Plaintiffs' expert Philip Russ is a consultant who works in the pharmaceutical industry. His opinions focus on the two finished dose manufacturer Defendants, Teva and Torrent (collectively, "the Finished Dose Defendants"). His report does not set forth opinions with respect to ZHP and he did not disclose any opinions with respect to ZHP prior to his deposition (as addressed in section III below). *See* 10/31/22 Report of Philip Russ ("Russ Rep.").[1]

Russ opines that the Finished Dose Defendants failed to establish the reliability of their active pharmaceutical ingredient ("API") supplier's test results and data and perform oversight of their API supplier, which he contends constituted deviations from current Good Manufacturing Practices ("cGMP") and other industry

[1] Philip Russ's October 31, 2022 report is attached to the accompanying Certification of Victoria Davis Lockard as **Exhibit A**.

standards. Moreover, though he did not offer the opinion that any Defendants' product was adulterated in his expert report, during his deposition he claimed—for the first time on redirect in response to leading questions from his counsel—that both ZHP's API and the finished dose product manufactured by the Finished Dose Defendants were "adulterated." None of Russ's opinions are the product of reliable methodology.

The Court should exclude Russ's opinions on the Finished Dose Defendants oversight of their API supplier and alleged failure to establish the reliability of their API supplier's test results for at least three reasons. ***First***, Russ's opinion is premised on his demonstrably incorrect assumption that the Finished Dose Defendants did not perform their own testing of ZHP's API throughout the entire time they manufactured valsartan containing drugs ("VCDs"). With respect to Teva, Russ ignored and declined to review the testing information contained in the very Annual Product Review documents he testified were "very important" and the "first thing you would ask to see" when performing an inspection, which documented the full specification testing performed by Teva on each and every lot of valsartan API received from ZHP. For Torrent, he declined to credit the sworn testimony of their corporate representative who indicated that such testing was similarly performed. His ignorance of the contradictory documentary and testimonial evidence most relevant to his opinions reflects a complete absence of reliable methodology.

Second, after being confronted at his deposition with a fatal flaw in his core opinion about the Finished Dose Defendants, Russ made a transparent attempt to pivot by arguing that the Finished Dose Defendants' testing of valsartan API—which he had previously been convinced was not performed—was not in fact the issue. He proffered rather that his real concern was whether the Finished Dose Defendants performed "comparative testing" and analyzed the raw results of their own chromatography in comparison to chromatography he assumes was available from ZHP. However, this opinion appears nowhere in his expert report and was plainly conjured up at deposition. The only references to "comparison" of any type in his report are two general statements that a finished dose manufacturer should compare *the results of testing* from its own analysis of API with the certificate of analysis received from the API manufacturer, and comparison of *the test results* obtained by the finished dose manufacturer on product manufactured using a new process with the data from product manufactured under a prior process in connection with a process change. This is exactly the type of "comparison" testing which was in fact performed by the Finished Dose Defendants here and, once again, conveniently ignored by Russ.

Third, Russ's claim that the Finished Dose Defendants should have identified the NDMA impurity from analysis of "raw chromatography" data—again offered for the first time at his deposition—directly contradicts Plaintiffs' own organic

chemistry experts, most notably Dr. Stephen Hecht, who confirmed that the size of the NDMA peaks at issue would have been too small to identify during chromatography analysis.

Russ also offered a host of opinions on the motive, intent, and state of mind underlying Torrent's decision to use ZHP's valsartan API. Black letter law holds that such opinions are outside the bounds of expert testimony and should be excluded.

Finally, the Court should exclude the opinions offered by Russ for the first time at his deposition, including his opinions on "adulteration" and all his opinions with respect to ZHP. These opinions are inadmissible because they were not properly disclosed in Russ's expert report, are inconsistent with Russ's own prior testimony that he did not intend to opine that ZHP's API or VCDs were adulterated, and constitute improper legal conclusions.

For all of these reasons, discussed further below, the Court should exclude Russ's proffered opinions in their entirety.

BACKGROUND

Russ is an industry consultant who has served as the Principal Consultant of his own firm, IcGXP, Inc., which includes no other employees, since 2008. 1/5/2023

Dep. of Philip Russ ("Russ Dep.") at 46:7-48:1.[2] In his expert report, Russ offered the following summary of his opinions with respect to the Finished Dose Defendants:

[redacted] Russ Rep. ¶ 2.

The following paragraphs of Russ's report describe [redacted]

[2] Philip Russ's January 5, 2023 deposition transcript is attached to the accompanying Certification of Victoria Davis Lockard as **Exhibit B**.

Russ specifically criticizes the Finished Dose Defendants for the following:

[redacted]

As was amply demonstrated throughout his deposition, Russ's core opinions and criticisms of the Finished Dose Defendants are predicated on his factually incorrect assumption that they did not perform independent testing and analysis of ZHP's valsartan API both during supplier qualification and throughout the lifecycle

of the VCDs. His methodology of declining to review and credit the most relevant documentary and testimonial evidence in this case and then assume that anything not discovered in his woefully limited review did not occur is the very definition of unreliable, and similar issues underlie all of the opinions presented in his report.

LEGAL STANDARD

Under Federal Rule of Evidence 702, this Court performs a "gatekeeping function" to ensure that all expert testimony is both relevant and reliable. *See In re Paulsboro Derailment Cases*, 746 Fed. Appx. 94, 98 (3d Cir. 2018) (Vanaskie, J.) (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993)). It is Plaintiffs' burden to show Russ's testimony is admissible. *See Warren Distributing Co. v. Inbev USA L.L.C*, 2010 WL 2179167, at *3 (D.N.J. May 26, 2010) (Kugler, J.) (citing *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)). The Third Circuit has explained that Rule 702 embodies a trilogy of restrictions on expert testimony: "qualification, reliability, and fit." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (internal quotations omitted).

In evaluating whether expert testimony satisfies the requirements of Rule 702, the Court "must make certain that [the] expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999); *see also*

Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996) ("[T]he courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it."). Under Rule 702, the expert's opinions must be the "product of reliable principles and methods" that have been "reliably applied . . . to the facts of the case." Fed. R. Evid. 702. This requires a review of both "an expert's methodology and the application of that methodology." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 792 (3d Cir. 2017). "[A]ny step that renders [an expert's] analysis unreliable . . . renders [his or her] testimony inadmissible." *Id.* at 797 (citation omitted); *see Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000) (proponent of testimony must show that the "reasoning or methodology underlying the testimony is scientifically valid and . . . that reasoning or methodology properly can be applied to the facts in issue") (quoting *Daubert*, 509 U.S. at 592-93); *In re Pharmacy Benefit Managers Antitrust Litig.*, No. 03-4730, 2017 WL 275398, at *17 (E.D. Pa. Jan. 18, 2017) ("The reliability prong 'applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, and the link between the facts and the conclusion.'") (quoting *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012)).

A court should not admit "evidence that is connected to existing data only by the ipse dixit of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *see also Montgomery County v. Microvote Corp.*, 320 F.3d 440, 448 (3d Cir. 2003)

("[Because] conclusions and methodology are not entirely distinct from one another . . . a 'court may conclude that there is simply too great a gap between the data and the opinion proffered.'") (quoting *Joiner*, 522 U.S. at 146). Nor should a court permit one expert to merely "parrot or act as a mouthpiece for other experts' opinions, without independent verification of those opinions." *Edmond v. Plainfield Bd. Of Educ.*, No. 11-cv-2805 (KM) (JBC), 2018 U.S. Dist. LEXIS 158980, at *14 (D.N.J. Sept. 13, 2018) (internal quotations omitted); *see also In re TMI Litig.*, 193 F.3d 613, 716 (3d Cir. 1999) ("unblinking reliance" by an expert on another's opinions "demonstrates that the methodology he used to formulate his opinion was flawed under Daubert as it was not calculated to produce reliable results"), as amended, 199 F.3d 158 (3d Cir. 2000).

In addition, the proponent of expert testimony must establish that the expert is qualified "to render an opinion" based on his or her "specialized expertise." *In re Hum. Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 655 (D.N.J. 2008) (citation omitted). Although qualification is interpreted liberally, the Third Circuit recognizes that an expert who "may be generally qualified" may nevertheless "lack qualifications to testify outside his area of expertise." *Calhoun*, 350 F.3d at 322. "While the background, education, and training may provide an expert with general knowledge to testify about general matters, more specific knowledge is required to support more specific opinions." *Id.*

Finally, plaintiffs must establish that the testimony "will assist the trier of fact" in understanding issues relevant to the case. *Id.*, at 321; see Fed. R. Evid. 702(a). This means that the testimony must have "a valid scientific connection" to, or "fit," the pertinent inquiry in the lawsuit. *Daubert*, 509 U.S. at 591-92; *Calhoun*, 350 F.3d at 321. "The issue of fit 'is one of relevance and expert evidence which does not relate to an issue in the case is not helpful.' . . . The standard for fitness is 'not that high' but is 'higher than bare relevance.'" *In re Hum. Tissue Prod Liab. Litig.*, 582 F. Supp. 2d at 657 (internal citations omitted).

ARGUMENT

I. Russ's opinions as to the Finished Dose Defendants' qualification and testing of ZHP's API and oversight of ZHP as an API supplier are unreliable and based on demonstrably flawed methodology.

Russ's central opinion as to the Finished Dose Defendants' conduct is that they did not comply with cGMP and industry standard because they failed to perform their own testing of ZHP's API, and rather relied on representations from ZHP or information contained in ZHP's certificates of analysis. As documented throughout this litigation and demonstrated at Russ's deposition, this central premise is false. Russ deliberately ignored the most important documentary and testimonial evidence showing that *the Finished Dose Defendants in fact performed their own testing on each and every lot of ZHP's valsartan API*.

This error is not a difference of opinion or a question of approach – it

represents an irreconcilable flaw in Russ's methodology and renders all of his opinions as to whether the Finished Dose Defendants testing and oversight of ZHP's API was appropriate not just unreliable, but factually incorrect. To state the obvious, he cannot be permitted to affirmatively misrepresent the record on a central issue to the jury under the guise of serving as an expert. Accordingly, his methodology is unreliable and his opinions set forth in paragraphs 2, 69-71, 73-79, 86-102, and 109-114, should be excluded.

A. Russ's opinions are predicated on incorrect assumptions he arrived at by ignoring the most central documentary and testimonial evidence in this litigation.

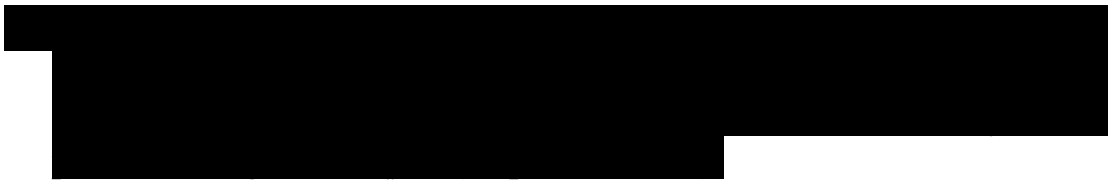
Expert testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue." *Daubert*, 509 U.S. at 591. Ordinarily, the question facing a Court in evaluating whether expert testimony will assist the trier of fact is whether the testimony fits the specific facts of the case and whether it risks confusing the jury. But Russ's opinions here present a more fundamental problem. Allowing Russ to offer the opinions set forth in his report which are predicated on the incorrect assumption (as he was forced to acknowledge during his deposition) that the Finished Dose Defendants did not perform regular, independent testing of ZHP's valsartan API in connection with qualifying ZHP as a supplier and during the manufacturing process would actively mislead the jury.

Russ's criticisms of the Finished Dose Manufacturers set forth in his report

are based on the assumption that no independent testing of ZHP's valsartan API occurred [redacted]

His specific criticisms with respect to the Finished Dose Defendants' supplier qualification of ZHP are similarly focused:

[redacted]



True to form, his criticisms of Teva specifically all presume that Teva did not test ZHP's valsartan API:

He reiterated that this was his central criticism of the Finished Dose Manufacturers throughout his deposition:

- "So it's trust but verify. So the regulation allows me to receive materials on a certificate of analysis, *but I must do some independent evaluation -- whether that be through testing or audits, data review* -- that would give me assurance about the reliability of that supplier and of -- and of

> the data that they are -- that underlies and supports the values they have provided me on a certificate of analysis." Russ Dep. at 128:10-18 (emphasis added).

- "[T]he industry standard -- and, again, the "C" or the "Current" in Good Manufacturing Practice, this is the standard practice that I see in my experience throughout industry that comparative -- *there's no other way to establish the reliability of test results if I don't look at any of the test results*." *Id.* at 136:21-137:2 (emphasis added).

At his deposition Russ was shown the Annual Product Review for one of Teva's VCDs, shortly after he had described the Annual Product Review as "one of the best, in my opinion, summary documents that points to all the records that [FDA] want[s] to see." Russ Dep. at 142:6-8. He had not reviewed any of the Annual Product Reviews produced by Teva, *id.* at 144:2-3, which he initially and repeatedly claimed simply reflected data copied over from ZHP's certificates of analysis, *id.* at 224:8-14, 225:16-19, 226:9-18, 229:24-230:6. Russ was shortly thereafter forced to begrudgingly acknowledge that the data in fact reflected the results of Teva's own testing. *Id.* at 231:17-234:21. Russ declined to look at any of the other Annual Product Reviews. *Id.* at 238:8-16.

Rather, Russ quickly pivoted to a new argument that the lack of testing, despite being the core criticism stated over and over again in his expert report and during his full day of deposition testimony, was not actually the issue:

> "If these results were produced by [Teva], then they were produced by [Teva]. I don't have an issue with that. I didn't opine that there was a concern with the regulatory requirement to do testing on drug substances or not based on reduced testing.

> . . . .
> My issue is not that they did testing or not. It appeared to me because I wasn't -- I didn't see data testing for batches, that they didn't do testing. My concern isn't that they didn't do testing. You are allowed to not do testing."

Id. at 234:22-236:1. He tried, somewhat incredibly, to state flatly that "I have not opined in my report that not doing testing is a problem." *Compare* Russ Dep. at 236:16-17, *with* Russ Rep. ¶¶ 69-71, 74, 76, 78-79, 88, 92, 98, 102.

Russ similarly disassembled and chose to discredit without analysis the evidence in the report of Torrent's expert Dr. Akhilesh Nagaich and the sworn testimony of Torrent's 30(b)(6) representative Dr. Sushil Jaiswal which confirmed that Torrent had also tested every batch of API it received from ZHP. Russ Dep. at 246:1-247:2. Russ once again disavowed the basis for his own expert report and tried to raise a new concern with regard to a lack of "comparative evaluation" of raw chromatography. *Id.* at 248:15-20.

Russ's new opinion on "comparative testing" offered at deposition in a transparent attempt to salvage his proffered opinions predicated on the Finished Dose Defendants having failed to independently test and evaluate ZHP's valsartan API is the product of no methodology beyond self-preservation, and is even more importantly not contained anywhere in his expert report. Fed. R. Civ. P. 26(a)(2)(B)(i); *see Krys v. Aaron*, 112 F. Supp. 3d 181, 207 (D.N.J. 2015) (an expert may not present new opinions on topics not timely included or otherwise disclosed

in the expert's report); *see also Johnson v. Vanguard Mfg., Inc.*, 34 F. App'x 858, 859 (3d Cir. 2002) (affirming exclusion of expert opinion not disclosed in report). The sole references to any sort of "comparison" testing included in Russ's report [redacted] This is precisely the type of analysis the Finished Dose Defendants performed by independently testing each batch of ZHP's valsartan API and confirming their results were within specification and similar to those produced by ZHP – analyses which Russ ignored during his review of materials in forming his opinions.[3]

As discussed below in part I.B, *infra*, none of Russ's opinions are the product of reliable methodology, but at a minimum he cannot be permitted to affirmatively misrepresent the record to the jury or offer new opinions not set forth in his expert

[3] Notably, Russ's attempt to salvage his liability opinions by claiming "comparative analysis" of chromatography would have enabled the Finished Dose Defendants to identify the presence of NDMA in valsartan API is directly contradicted by Plaintiffs' own organic chemistry experts, most notably Dr. Stephen Hecht. 7/6/2021 Report of Stephen Hecht at 20 ("In their analyses of the product, ***they would not have identified NDMA in the chromatograms unless they were specifically looking for it, because the peaks would be too small.***" (emphasis added)). Like the rest of his opinions offered only at his deposition, there is no discernible methodology supporting Russ's conclusion that NDMA peaks would have been visible on analysis of chromatography, and he cannot be permitted to contradict not only Defendants' but Plaintiffs' own organic chemistry experts who did in fact address this topic in their reports.

report when confronted with clear, substantive errors in his analysis.

B. As demonstrated by his failure to appreciate the critical evidence of the Finished Dose Defendants' testing of valsartan API, Russ's opinions are the product of no discernible or reliable methodology.

As the above example illustrates, Russ's opinions are unreliable because he employed no discernible methodology or expertise in arriving at his ultimate conclusion. At his deposition, Russ conceded his "methodology" was as follows: First, he asked for specific documents, which he did not receive or was told did not exist. Second, because the specifically requested documents were not produced to him, he assumed they did not exist and assumed that whatever was purported to be reflected in those documents did not occur. Put differently, based on the absence of the requested documents, Russ concluded that the Finished Dose Defendants did not undertake any of the steps required by cGMPs or industry standards—steps he assumed would have been reflected in these documents. *See, e.g.*, Russ Dep. at 144:2-8, 22-24; 234:22-236:1. The myriad problems with this "methodology" are shown most clearly based on the critical factual error Russ's approach led to for Teva's testing as detailed in section I.A, *supra*. And when similarly confronted with evidence from at least one Torrent witness that contradicted his opinion, he simply did not credit the sworn testimony. *See id.* at 246:1-247:2, 248:15-20.

Ignoring the best available evidence and instead relying on continually shifting justifications for pre-determined "expert" opinions in the absence of any

meaningful analysis or consistent approach does not reflect a coherent methodology and calls into serious question whether Russ can be allowed to reliably present *any* testimony whatsoever to the jury. [redacted] This absence of rigor may be permissible in his role as an un-supervised consultant, but it is not sufficient to allow Russ's opinions to reach the jury. *See* Fed. R. Evid. 702(a); *Daubert*, 509 U.S. at 591-92; *Calhoun*, 350 F.3d at 321; *In re Hum. Tissue Prods. Liab. Litig.*, 582 F. Supp. at 655.

II. Russ should not be permitted to offer expert opinions purporting to comment on Torrent's motivation, intent, and state of mind.

Russ's opinions on Torrent's motivation, intent, and state of mind in accepting valsartan API are improper and should be excluded. It is black letter law that "[e]xpert witnesses are not 'permitted to testify . . . regarding [a party's] intent, motive, or state of mind, or evidence by which such state of mind may be inferred." *AstraZeneca LP v. Tap Pharm. Prods., Inc.*, 444 F. Supp. 2d 278, 293 (D. Del. 2006) (quoting *Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 443 (D. Del. 2004)); *see also Warren Distrib. Co. v. InBev USA L.L.C.*, No. CIV.07-1053RBK/JS, 2010 WL 2179167, at *6 (D.N.J. May 28, 2010) ("An expert cannot testify about a person's intent, motive, or state of mind."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) (holding "[i]nferences about the

intent or motives of parties or others lie outside the bounds of expert testimony"); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000) ("The question of intent is a classic jury question and not one for experts . . . ."). These opinions are generally excluded because "opinions of these witnesses on the intent, motives or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise," and, therefore, "lie outside the bounds of expert testimony." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d at 546-47.

Russ's report offers a host of improper opinions on Torrent's state of mind, intent, or motivation. For example, Russ opines that [redacted] According to Russ, Torrent also [redacted] And Russ further opines that [redacted] Russ's deposition testimony confirms that he offers improper opinions on Torrent's motivations:

> Q. Are you offering anything about Torrent's motivation in accepting ZHP Valsartan API?

THE WITNESS: I certainly am in this paragraph [106].

Russ Dep. at 278:18-23 (objection to form omitted).

Accordingly, Russ's opinions on Torrent's state of mind, intent, and motivations should be excluded. *See, e.g.*, *Oxford Gene Tech. Ltd.*, 345 F. Supp. 2d at 443 n.9 (expert cannot opine as to what defendant "recogniz[ed]," what a defendant may have felt, or what a defendant may have been "concerned" with); *AstraZeneca LP*, 444 F. Supp. 2d at 293 (excluding testimony on the intent of a party, including statements that a party was "seeking to utilize" certain documents and that a party "'aimed' to elevate the importance of certain data"); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d at 545-47 & n. 38, 40 (excluding testimony that certain actions were motivated "by profit"); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *9 (excluding testimony that a pharmaceutical defendant's conduct related to labeling was motivated by a desire to increase profits).

III. Russ may not offer unsupported opinions about ZHP or "adulteration" because they were not disclosed in his report.

Russ should also be prohibited from opining that ZHP's API, and VCDs incorporating it, were adulterated while they were on the market because these opinions: (1) were not disclosed in his expert report; (2) are based solely on Russ's own say-so; and (3) constitute improper legal conclusions.

First, Russ failed to properly disclose any opinions about adulteration – or ZHP generally – in his expert report. It is well recognized that an expert report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i); *Krys*, 112 F. Supp. 3d at 207 (an expert may not present new opinions on topics not timely included or otherwise disclosed in the expert's report); *see also Johnson*, 34 F. App'x at 859 (affirming exclusion of expert opinion not disclosed in report).

Russ's report does not include any opinion that VCDs or ZHP's valsartan API were adulterated. *See generally* Russ Rep. Indeed, Russ admitted at his deposition that he did not disclose any adulteration opinions, stating: "I don't offer an opinion in my report about the specific adulteration of a product." Russ Dep. At 91:6-7; *see also id.* at 92:23-95:1 ("The determination of a product being adulterated itself is – is not something I am opining on in my report. . . . Q. "[Y]ou are not going to give the opinion that any of the product manufactured by Teva was adulterated?" A. "No, I am not."). Moreover, Russ's report does not include ***any*** opinions related to ZHP. According to Russ's report, he was asked only to [redacted] (*see* Russ Rep. ¶ 1; *see also* Russ Dep. At 16:23-17:8), and as a result, did not include any analysis of ZHP's conduct or its API product. Russ also stated multiple times at his deposition that he did not intend to offer opinions about any defendant other than Teva or Torrent, including ZHP

specifically (*see* Russ Dep. At 307:21-308:8; 313:6-14), and agreed that he was not "offering any opinions about the quality of ZHP Valsartan API" (*id.* at 278:12-16).

It was only in response to leading questioning by plaintiffs' counsel at the end of his deposition that Russ changed course and testified that ZHP's API was adulterated because it "was identified to have a genotoxic impurity." *See id.* at 314:5-17; 326:6-327:8; 341:14-22; 342:11-343:17. Notably, Russ admitted that his report does not state anywhere that ZHP's API was adulterated while it was on the market because it contained a genotoxic impurity or for any other reason. *See id.* at 343:19-345:10. Accordingly, such opinions were not properly disclosed and should be barred at trial.

Second, even if Russ had disclosed his untimely opinions, they are still inadmissible because they are based "on his own ipse dixit, rather than on something more readily verifiable." *In re TMI Litig.*, 193 F.3d 613, 687 (3d Cir. 1999). Russ took the position at his deposition that ZHP's API, and VCDs that included it, were adulterated because the API "was identified to have a genotoxic impurity. For me, that is adulterated product. Period. End of sentence. No further discussion or evaluation needed." Russ Dep. at 342:11-343:17. But Russ has not identified ***any*** scientific, regulatory or other support for the proposition that the mere presence of a genotoxic impurity in a product, even at trace amounts, renders a product adulterated – much less that this was the case at the time ZHP's API was on the market.

Accordingly, Russ's opinions about ZHP and adulteration are based entirely on his own say-so, and are inadmissible for this reason too.

Finally, Russ's opinions that ZHP's API and VCDs were adulterated under applicable regulations should be excluded because they are improper conclusions of law, not proper expert testimony. *See Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006).

The "prohibition on experts testifying as to their own legal conclusions is so well established that it is often deemed a basic premise or assumption of evidence law—a kind of axiomatic principle." *Holman Enters. v. Fid. & Guar. Ins. Co.*, 563 F. Supp. 2d 467, 472 (D.N.J. June 30, 2008) (*citing United States v. Leo*, 941 F.2d 181, 196-97 (3d Cir. 1991). Numerous courts around the country, including this Court just weeks ago, have refused to allow expert witnesses to offer opinions about a pharmaceutical company's compliance with FDA regulations, including opinions as to whether medications were "adulterated or misbranded." ECF No. 2261 at 93; *see also, e.g., Robinson v. Ethicon, Inc.*, No. H-20-03760, 2022 U.S. Dist. LEXIS 36441, at *20 (S.D. Tex. March 2, 2022) (regulatory expert prohibited from offering opinions that product was misbranded or adulterated, as these are impermissible legal conclusions); *In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prods. Liab. Litig.*, MDL No. 2436; Case No. 2:12-cv-07263, 2016 U.S. Dist. LEXIS 98858, at *8–9 (E.D. Pa. July 27, 2016) (excluding an expert opinion as to whether

a drug met a certain standard pursuant to FDA regulations, as such "would require a legal interpretation" of that standard); *Tsao v. Ferring Pharms., Inc.*, No. 4:16-cv-01724, 2018 WL 3649714, at *11 (S.D. Tex. Apr. 19, 2018) (opinion by regulatory expert that drug was "misbranded" was "inadmissible legal conclusion[]."); *Stanley v. Novartis Pharms. Corp.*, No. 11-03191, 2014 U.S. Dist. LEXIS 198861, at *10 (C.D. Cal. May 6, 2014) (precluding an expert from "offer[ing] legal conclusions, including whether Defendant was in regulatory compliance with the FDCA"); *In re: Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 557 (S.D.N.Y. 2004) (holding that opinions regarding "the duties of pharmaceutical companies are not appropriate expert testimony because they embrace ultimate questions of law outside the province of an expert").

Russ's assertion at his deposition that ZHP's API, and VCDs containing that API, were adulterated at the time of sale is precisely the type of legal/regulatory opinion barred under Third Circuit law. It should be excluded for this reason as well.

CONCLUSION

For the foregoing reasons, Russ's opinions, specifically those set forth in paragraphs 2, 69-71, 73-79, 86-102, and 109-114 of his expert report and that were stated for the first time at his deposition, should be excluded. As the remaining portions of his report contain nothing more than factual narrative and citations to primary documents, to the extent this information is admissible it can and should be

submitted to the jury directly for consideration. Accordingly, Defendants respectfully request that the Court exclude the opinions of Plaintiffs' expert Philip Russ in their entirety.

Dated: March 13, 2023

Respectfully Submitted:

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CERTIFICATE OF SERVICE

I hereby certify that on March 13, 2023, a copy of the foregoing document was servedon all counsel of record via CM/ECF.

By: */s/ Steven M. Harkins*
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